DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 20, 2015

Stanmore Worldwide Implants, Ltd.
Mr. Dan Clarke
Regulatory and Compliance Officer
210 Centennial Avenue
Centennial Park
Elstree WD6 3SJ
United Kingdom

Re: K140898
Trade/Device Name: Patient Specific Distal Femur
Regulation Number: 21 CFR 888.3510
Regulation Name: Knee joint femorotibial metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KRO
Dated: December 19, 2014
Received: December 22, 2014

Dear Mr. Clarke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K140898

Device Name: Patient Specific Distal Femur

Indications for Use: The Patient Specific Distal Femur is intended for the replacement of diseased or deficient bone in the distal femur. It is indicated for:

- Limb salvage procedures where radical resection and replacement of the bone is required
- Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis
- Correction of varus, valgus or post traumatic deformity
- Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
- Ligament deficiencies
- Tumor resection
- Revision of previously failed total joint arthroplasty
- Trauma

The Patient Specific Distal Femur and its components are for single use only.

The Patient Specific Distal Femur and is components are for cemented use only.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Device Proprietary Name:	Patient Specific Distal Femur
Common Name:	Prosthesis, Knee, Femorotibial, Constrained, Cemented, Metal/Polymer
Classification Regulation:	21 CFR 888.3510
Product Code:	KRO
Submitter's Name:	Stanmore Worldwide Implants Ltd.
Address:	210 Centennial Avenue Centennial Park Elstree WD6 3SJ UNITED KINGDOM
Contact Person:	Ed Spearpoint
Telephone Number:	+44-20-8238-6500
Fax Number:	+44-20-8953-7443
Date Summary Prepared:	January 15, 2015

Device Description

The Patient Specific Distal Femur is a patient-specific system that is intended for the replacement of diseased or deficient bone in the distal femur. The Patient Specific Distal Femur and its components are intended for cemented use only. The system is comprised of a range of stems, collars coated with hydroxyappetite (HA) or without coating (stippled or smooth), a range of shafts, femoral components (including axle, bushes and circlip), bumpers and a femoral epiphysis component, (i.e. SMILES TKR).

The materials used in the manufacture of the Patient Specific Distal Femur include titanium alloy (Ti-6Al-4V), cobalt-chromium-molybdenum (Co-Cr-Mo) and ultra-high molecular weight polyethylene (UHMWPE).

The device is for single use only.

Purpose of Submission

This Premarket Notification is being submitted as a modification to the METS® Modular Distal Femur to add patient-specific components and an extra-small option for the knee.

Intended Use
The Patient Specific Distal Femur is intended for the replacement of diseased or deficient bone in the distal femur. It is indicated for:

- Limb salvage procedures where radical resection and replacement of the bone is required
- Painful and disabled joint resulting from avascular necrosis, osteoarthritis, rheumatoid arthritis or traumatic arthritis
- Correction of varus, valgus or post traumatic deformity
- Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
- Ligament deficiencies
- Tumor resection
- Revision of previously failed total joint arthroplasty
- Trauma

The Patient Specific Femur and its components are for single use only.

The Patient Specific Distal Femur and its components are for cemented use only.

Predicate Device(s)
The predicate devices are the METS® Modular Distal Femur, cleared on September 19, 2012 (K121029), the JTS® Extendible Distal Femoral Implant cleared on March 22, 2011(K092138) and the JTS® Extendible Distal Femoral Implant cleared on January 22, 2014 (K133152).

Technological Characteristics
The Patient Specific Distal Femur is a patient-specific implant system that is used to replace diseased or deficient bone in the distal femur. Every configuration includes a knee, femoral shaft, femoral stem and collar.

The Patient Specific Distal Femur is based on the surgeon's prescription and the patient radiological information. The implant is designed and manufactured for each patient.

The Patient Specific Distal Femur is provided sterile by gamma irradiation.

Substantial Equivalence
The Patient Specific Distal Femur has the same intended use and technological characteristics as the METS® Modular Distal Femur (K121029). The difference between the two implant systems is that the current version includes patient-specific components. These new components have been cleared previously by FDA as part of the JTS® Extendible Distal Femoral Implant (K092138 and K133152).

Performance Data

The Patient Specific Distal Femur has been evaluated through non-clinical performance testing for disassembly of the distal femur and fatigue and wearing testing of the knee. The Patient Specific Distal Femur met all of the acceptance criteria.

The Patient Specific Distal Femur does not alter the fundamental scientific technology of the METS® Modular Distal Femur, alter the indication for use or raise any new questions of safety or effectiveness. Therefore, the Patient Specific Distal Femur is substantially equivalent to its predicate device.